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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,895	03/20/2006	Yukiyo Sekimoto	2008_1706	1331

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EXAMINER	
MELLER, MICHAEL V	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
06/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,895	SEKIMOTO ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,12,13,17 and 18* is/are pending in the application.

4a) Of the above claim(s) *7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12,13,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election **without traverse** of Group I, claims 1-6, 12, 13 in the reply filed on 12/4/2007 is acknowledged.

Claims 7 and 8 remain withdrawn from further consideration as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-5, 12, 13, 17, 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a soy isoflavone aglycone wherein the soy isoflavone aglycone is obtained from or in an extract from whole-grain soy; the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1, and the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90 %. Thus, the claims are drawn to a genus of compounds that is defined only by a nebulous percent and a nebulous ratio.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factors present in the claims are drawn to a soy isoflavone aglycone which is obtained from or in an extract from whole-grain soy; the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1, and a soy isoflavone aglycone where the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90 %. The specification gives no indication how such an amount of genistein and daidzein was obtained. In fact applicants have stated on the record that such an amount of genistein to daidzein does not naturally exist thus there is nothing on the record to show one of ordinary skill in the art that applicants had possession of the claimed invention at the time the invention was made since there is nothing to teach one of ordinary skill in the art in the specification

how to identify such a compound. Without knowing what the compound's structure is, it is not in the possession of applicants. How can applicants be in possession of the claimed soy isoflavone aglycone “wherein the soy isoflavone aglycone is obtained from or in an extract from whole-grain soy" if applicants have stated on the record that the claimed compound is not always obtainable from soybeans as claimed ? Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of inhibitors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 12, 13, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovett (US 6881419) in view of USDA-Iowa State University Database on the Isoflavone Content of Foods 1999 (hereafter, "USDA").

Lovett teaches that Vitamin D3, calcium and soy isoflavones (which inherently contain compounds such as genistein and daidzein) are in the same composition, see table 1.

Note that about 27 % of calcium is used in the composition of Lovett, 2.6×10^{-4} % of Vitamin D^3 and about 2.4 % of soy isoflavones are used in the composition (when calculated with respect to the total composition).

Lovett does not teach the specifically claimed ratio of genistein/daidzein and the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90 %.

USDA teaches that soy flour, full-fat, raw contains 71.19 of daidzein, 96.83 of genistein and thus has a ratio within the claimed amount and a total weight of genistein and daidzein in the soy isoflavone aglycone which is at least 90 % exists in USDA, see NDB No. 16115 of USDA.

Thus, it would have been obvious at the time the invention was made to use the soy isoflavone (which inherently contains aglycones since isoflavones are contained in soybean or soy foods in two chemical forms, i.e., aglycones and glucosides) of USDA in the invention of Lovett since USDA makes it clear that such amounts of genistein and daidzein were well known at the time the invention was made to exist in the claimed

amounts. Clearly it was well within the purview of the ordinary artisan to do this since USDA is teaching such a well known soy flour which is well known as a source of soy isoflavones and clearly within the purview of the ordinary artisan to use as a well known source of soybean.

It is noted that USDA 2007 provided by applicant contains the same data on NDB NO. 16115 as does USDA 1999 thus making USDA 1999 still a valid reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/
Primary Examiner, Art Unit 1655